Amendments to the Drawings:

The attached sheets of drawings include changes to Fig. 3A-3E, Fig. 17 and Fig. 19.

The sheet, which includes Fig. 3A-3E, replaces the original sheet including Fig. 3A-3A. In Fig 3A-3E, previously absent Legend "Prior Art" is sought to be added.

The sheet, which includes Fig. 17, replaces the original sheet including Fig. 17. In Fig 17, reference numeral 49 is sought to be deleted.

The sheet, which includes Fig. 18 and 19, replaces the original sheet including Fig. 18 and 19. In Fig 19, reference numeral for head, which was previously obscured by page margin is sought to be added.

Attachment: Three Replacement Sheets

Remarks/Arguments

Claims 13-22 and 24-27 were examined in the outstanding non-final office action mailed on 06/18/2009 (hereafter "Outstanding Office Action"). All claims were rejected. By virtue of this paper, claims 13, 14, 16-18, 21-26 and 28-29 are sought to be amended, claims 15, 19, 20 and 27 were previously presented and withdrawn claims 23, 28 and 29 are sought to be currently amended to further clarify applicant's invention and to include all the limitations of generic claim 13 to allow rejoinder of these claims.. The amendments and additions are believed not to introduce new matter, and their entry is respectfully requested. The cancellations and amendments are made without prejudice or disclaimer. Claims 13-29 are respectfully presented for consideration further in view of the below remarks.

Priority

The disclosure of foreign application, Application No. 438/MUM/2004 (filed on 12 April, 2004), was noted by Examiner as failing to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application, and specifically as failing to provide support for claims 13-22 and 24-27.

It is noted that the subject patent application also claims priority from PCT application PCT/IN2005/000103 filed on 7 April 2005. It is accordingly Applicants understanding that each claim is entitled to the priority date of either 12 April 2004 or 7 April 2005. Continuation of Examination of claims 13-22 and 24-27 based on priority claim to at least the PCT application, is respectfully requested.

Information Disclosure Statement

The document PCT/EP98/01018 to Hinze in the earlier-submitted information disclosure statement was not considered, for not being properly identified by publication number. The document cited as 19707420 to Hinze was not been considered because the country code was not identified. A fresh 1449 form citing the documents correctly and with country code is submitted along with this paper.

It is respectfully noted that these two are foreign documents, copies of which have been already submitted (with a previously filed IDS), and thus it is requested that the two documents be considered and made of record, without requiring additional fees.

Drawings

Figures 3A-3E were required to be designated with the legend "Prior Art". The drawings were objected to as failing to comply with 37 CFR 1.84(p)(5) because Fig. 17 included a reference character "49" not mentioned in the description. The drawings are objected to because Fig. 19 contained a line at the head of the femur which was missing a reference character. Replacements sheets for Figures 3A-3E, Figure 17 and Figure 19 are attached along with this paper.

The drawings were objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "44" had been used to designate both a shaft part and a threaded part. Applicant notes that reference numeral 44 – shaft part and threaded part – both are same- shaft part is having threads.

The amendments to the drawings and specification are believed not to introduce new matter and their entry is respectfully requested. Withdrawal of the objections with respect to Drawings is respectfully requested.

Specification

A substitute specification and abstract in proper grammar are submitted herewith. A marked version showing deleted material as crossed out lines and added material as underlining and also a clean version of substitute specification and abstract are submitted herewith. The substitute specification and abstract contain no new matter. Applicant respectfully requests Examiner to enter substitute specification and abstract.

Claim Objections

Appropriate correction and amendment of all objected claims are done to meet requirements of Examiner. Applicant respectfully request withdrawal of claim objections and allow entry of

amended claims.

Claim Rejections - 35 U.S.C. § 112

On page 10-11 of Non Final Office Action mailed on June, 18, 2009 , the Examiner rejected Claims 1**3,14 and 17** under 35 U.S.C.§ 112 , first paragraph . The Examiner is thanked for continuing examination, and thereby furthering prosecution. The Examiner has pointed out that the claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Examiner has further pointed that each of these claims recite that the ductility is at least 15% and the ultimate tensile strength is at least 600 MPa, however, Applicant's disclosure only provides support for a ductility between 15% and 25% and an ultimate tensile strength between 600 MPa and 800 MPa.

Applicant respectfully argues that original specification as filed provides support for amendments in claim 13, 14 and 17, for example Applicant describes on page 1 paragraph [1] ,lines 1-7 of published application **US 2007/0173834 A1** "The present invention relates to an orthopedic implant assembly used to repair fractures of the long bones particularly in children and in certain conditions in adults by generally more than one flexible intramedullary nails having very high flexibility with high tensile strength and gliding conical pathfinder tip at both ends.....".

Same way applicant discloses on page 3 paragraph [25] "1. As mentioned in background of art, a flexible nail to be used for long bones of children requiring side angled entry requires utmost flexibility or elasticity. Prior art nails or pins does not provide required ductility (percentage of elongation on mechanical testing) leading to either difficult entry as in Rush pin (8), straightening of curvatures of bone as in Ender's nail (11), requirement of opposing balancing nails of identical curvature of almost same cross section diameter having two different entry points at same level or otherwise possible mal-relation of fracture fragments as in - TENs (16)."

Other example is on page 3 paragraph [0032] "Invention provides straight flexible intramedullary nail (19) of universal length of 50 cm having 15 to 25 % of elongation on testing

on universal testing machine and ultimate tensile strength of about 600 to 800 MPa (Mega Pascal).".

Another part of description on page 4 paragraph [0039] describes and supports "1. Due to high flexibility, entry of flexible nail (19) in medullary canal (7) becomes easy and it preserves normal anatomic curvatures of long bones. It does not require opposing balancing identical curvatures and same level two different side entries with use of almost equal cross section diameter of flexible nails. It is introduced with single entry point (24) with lazy "s" shape (29) curvature and "c" shape curvature (30) of any appropriate diameter according to diameter of medullary canal with good elastic stability and without any malrelation of fracture fragments."

Further support in description is on page 5 paragraph [73] discloses "As shown .....It is processed by cold method to get higher ductility than titanium and also high ultimate tensile strength. It is made by drawing from ingot. Fig 4B, 4C 4D, 7A, 7B, 8A, 8B, 9, 10 shows its flexibility when inserted in medullary canal (7). Final product Flexible Nail (19) should have 15-25% of elongation and about 600 to 800 MPa (Mega Pascal) ultimate strength on testing done by universal testing machine. .....diameter or curvatures (26)."

Above specified passages of description as filed reasonably shows the purpose and objective of invention to have flexible nails having *very high flexibility* (structural property of at least 15% of elongation of final end product of flexible nail on tensile stress) and *very high strength* (structural property of at least 600MPa ultimate tensile strength) and knowledge and level of skill in art would permit one skilled in art to immediately envisage the product of flexible nail as claimed and disclosed in description. Applicant further argues that description supports the broad meaning for elements of claim in question and that broadening in claim is not outside the stated purpose of invention as described in specification as originally filed. Description supports for structural property of flexible nail having ductility of at least 15% inherently and description also describes its function and purpose to prevent malrelation of fracture fragments. Applicant further argues that applicant has found out one of the reasons for the problem in prior art of malrelation of fragment and that is due to low flexibility of prior art nails and has described in specification to have higher flexibility with structural property of

flexible nail having at least 15% of elongation of nail on tensile stress *as solution* to such problem as described in various paragraphs of description as stated above. Applicant nowhere teaches expressly or inherently in description or gives any suggestion or motivation that structural property of flexible nail having ultimate tensile strength above 800 MPa is undesirable or detrimental to function of flexible nail of claim. Applicant has described to have ultimate tensile strength of *about* 600-800 MPa as one of example of structural property and at various instances mentioned in description strongly in purpose of invention to have *very high strength* of flexible nail to have better function as stated above in example of various paragraphs of description. Applicant further argues that Art in question is mature enough and structural limitations claimed in claim and description distinguish the claimed invention from cited art and description as filed in this application leads to one skilled in present art to conclusion that the applicant is in possession of claimed limitation at the time of application filed. Applicant further argues that as applicant's specification need not describe the claimed invention in *ipsis verbis* to comply with the written description requirement and limitation may not however be imported into the claims from the specification and a claimed invention flexible nail of applicant is adequately described in the original specification at Paragraphs [1],[25],[32],[39] and [73] of published application **US 2007/0173834 A1** and that *reasonably* conveys to a person having ordinary skill in the art that the applicant had possession of the subject matter later claimed. Applicant respectfully requests with particular above mentioned facts of case of applicant's application to withdraw rejection of claims 13, 14 **and 17** under 35 U.S.C.§ 112 , first paragraph and allow entry of these claims.

On page 11 of Non Final Office Action mailed on June, 18, 2009, the Examiner rejected Claim **27** under 35 U.S.C. § 112, second paragraph. Applicant has amended said claims so that there is proper antecedent basis and to further defines Applicant's invention. No new matter has been introduced and the amended claims, which are believed to overcome the rejection under 35 U.S.C. § 112, second paragraph.

Claim Rejections - 35 U.S.C. § 101

Applicant has amended claims to avoid rejections of claims under 35 U.S.C. § 101. Applicant respectfully request withdrawal of claim rejection under 35 U.S.C. § 101 and allow

entry of amended claims.

Claim Rejections - 35 U.S.C. § 102

On page 12-13 of the Outstanding Office Action **Claim 13-16** were rejected under ***35 U.S.C. § 102(b)*** as being anticipated by "Vicenzi."(US 5,281,225). Applicant respectfully requests entry of amended independent Claim 13 and dependent claims 14-16.. Claim 13-16 have been amended to further describe Applicant's invention. Support for such amendments may be found throughout the specification, at, e.g., paragraphs [[0001], [0023],[0025],[0026],[0032],[0035],[0039],[0073],[0077], Figs. 4,5,7,8, and 9. Applicant submits that "Vicenzi." (US 5,281,225) do not suggest or teach or disclose each and every feature or element of amended claim 13-16. For example "Vicenzi." does not teach or suggest Intramedullary Pin 1 of *universal length* as elastic stems 8 are attached with one rigid stub 2 at one end. With this structure one cannot use same length nail in all the patients with different length of bone in different age group , so according to teachings of Vicenzi one who wants to use Intramedullary pin 1 requires to have all different length size inventory ready all the time for proper operation of Intramedullary pin in different age group and size of patients which is contrarily to disclosure by Applicant . If one intends to use universal length Intramedullary pin1 according to teachings of "Vicenzi.", one has to cut distal free ends 9 of stems 8 exactly according to size of patient preoperatively before insertion of intramedullary pin1 in medullary canal of a bone as proximal ends are held rigidly with rigid stub 2 , it will be very difficult to glide leading cut ends in medullary canal which does not serve the purpose as disclosed by Applicant. "Vicenzi" teaches Intramedullary pin 1 having elastic stems **8** where each stem 8 is *rigidly attached* with rigid metal stub 2 at one end and each stem 8 having other free end 9 which is *round* in shape at tip .Applicant discloses in amended Claim 13-16 Intramedullary flexible Nail 19 having *structurally* a shaft 31 , proximal end 32 and distal end 23 where *both* ends are *identical* and *free without any attachment* and both end are having *conical* pathfinder tip 20 which has cross section diameter less than shaft part for easy gliding in medullary canal of a bone during insertion . Applicant also points out that Intramedullary Pin 1 disclosed by Vicenzi is having stems 8 *bundled* before insertion into medullary canal of a bone with the help of means 10 comprising metallic wire 11, a manual grip ring 12 rigidly associated with wire

11 at one end and a bent portion 13 engaged on wire 11 defining loop 14 rigidly associated with wire 11 at other end , proximate to the ends stems 8 have respective grooves 15 in which loop 14 can be accommodated while wire 11 runs between stems 8 (Fig 4 and Fig 5) , it becomes very difficult to pass *bundled* nail across the fracture zone without broaching the canal and may require opening the fracture site by putting the cut in skin and structures up to bone at fracture zone leading to invasion to patient and have difficulty to unbundle the bundled inramedullary pin by pulling the wire 11 or there may be breakage of wire 11 or there may be breakage of stem 8 at groove 15 which is stress riser point in stem giving the notch effect while unbundling the intramedullary pin 1. Applicant further points out that as taught by Vicenzi proximal ends of stem 8 are rigidly associated with rigid stub there is *no possibility* to *align individual stem* 8 in relation with each other to reposition and align bone fragments of a fractured bone to prevent malrelation of fragments and individual stem end cannot have different curvature at different planes to have multiple contact points of fixation as they are bundled at end . Applicant further points out that intramedullary pin 1 as disclosed by Vicenzi is having rigid stub 2 rigidly associated elastic stems 8 having stress riser at junction (transitional zone of weakness) of rigid stub 2 and elastic stems 8 leading to breakage at junction while insertion of bundled intramedullary pin 1 or particularly while extracting unbundled intramedullary pin 1. Applicant further points out that Vicenzi teaches Intramedullary Pin 1 having rigid stub 2 and elastic stems 8 rigidly attached with stub 2 are made from 316 L Stainless Steel material but Vicenzi has not disclosed elastic stems 8 or rigid stub 2 having ductility of 15% elongation on tensile stress showing *structural property* of *final finished end product* of Intramedullary Pin 1. Examiner has taken the position that as Vicenzi 's Intramedullary Pin 1 is made from same material (316L Stainless Steel) as Applicant's Flexible Nail and ductility and ultimate tensile strength are the material properties of 316L Stainless Steel-material from nail is made , therefore extrapolated and *speculated* that Vicenzi's Intramedullary Pin is also having ductility of 15% of elongation on tensile stress . Applicant respectfully argues that Flexible Nail disclosed in amended claims 13-16 discloses *structural properties* of Applicant's Nail as final finished end product having *structural property* of at least 15% elongation of nail on tensile stress irrespective to *material property* of source material(for example, 316 L Stainless Steel) from which nail is made. Vicenzi's Nail is *structurally* and *functionally* different than Applicant's disclosure. Accordingly, Vicenzi does not

teach or describe, expressly or inherently, each and every element as set forth in amended claims 13-16 nor does `Vicenzi have elements arranged as required by these amended claims 13-16. As such, Vicenzi does not anticipate or render obvious independent claim 13 or dependent claims 14-16. Applicant respectfully requests entry and allowance of Claims 13-16.

On page 13-14 of the Outstanding Office Action **Claim 24** was rejected under ***35 U.S.C. § 102(b)*** as being anticipated by "Walker."(US 4,457,301 A). Applicant respectfully requests entry of amended independent Claim 24. Claim 24 have been amended to further describe Applicant's invention. Support for such amendments may be found throughout the specification,at,e.g.paragraphs[[0031],[0038],[0075],Figs.11A,11B,12A,12B,13,14,15,16,17,18 and 19. Applicant submits that "Walker." (US 4,457,301 A) do not suggest or teach or disclose each and every feature or element of amended claim 24. For example "Walker" teaches to have core 13 is made from either *plastic or ultra high molecular weight polyethylene* (Col. 5 ll 20, Col. 6 ll 11-12) and is *flexible relative to pins* 11 (Col 2. ll 6-7) and it *extends across* the fracture zone and *extends along* essentially whole length of pin (Col. 3 ll 48-51, Fig. 1, 2, and 10.). Applicant discloses a *proximal* fixation device which is made from *Stainless Steel Rod* and is *rigid relative to flexible pins* and *does not extend across* the fracture zone (Fig. 11A, 12A, 17, 18 and 19.) and *does not extend along* essentially whole length of flexible pins to have curvatures at different points and in different planes to get multiple contact point fixation inside the medullary canal without disturbing the fracture zone and to have flexible but stable construct. Plastic core relatively flexible to metal pins and metal pins *both extending across fracture zone* as taught by " Walker" *structurally or functionally* will not be able to allow to have curvatures at different points and planes to get multiple contact points of fixation inside the medullary canal, which is contrary to Applicant's disclosure. Plastic core and metal pins as having sliding fit taught by "Walker" will lead to plastic debris or wear at fracture zone due to friction between different material having different material properties leading to osteolysis – loss of bone at fracture zone which will delay or abort the healing of bone. Applicant further points that "Walker" *does not disclose element* of an *end cap* which is essential for proximal anchorage of proximal ends of flexible pins for rotational stability and to prevent sliding of flexible pins proximally *irritating soft tissue* leading to pain to the patient requiring early removal *before complete fracture healing.* 'Walker" teaches *sliding fit* of flexible pins in longitudinal grooves of flexible core (Col.5 ll 15-16) allowing sliding and migration of pins

proximally and also teaches to keep pins outside the flexible core at proximal insertion point or entry without *any anchorage* with flexible core for easy gripping for removal later on.(Col.3 ll 53-56) which is contrarily to teachings disclosed by Applicant. Walker's flexible core with pins is *structurally* and *functionally* different than proximal fixation device disclosed in amended claim 24 by Applicant. Accordingly, Walker does not teach or describe, expressly or inherently, each and every element as set forth in amended claims 24-26 nor does "Walker" have elements arranged as required by these amended claims 24-26. As such, Walker does not anticipate or render obvious independent claim 24 or dependent claims 25-26. Applicant respectfully requests entry and allowance of Claims 24-26.

Claim Rejections Under 35 U.S.C. § 103

Claims 17-19,21 are rejected under **35 U.S.C. 103(a)** as being unpatentable over Vicenzi**, (US 5,281,225 A)** in view of Walker (**US 4,457,301A**). Applicant respectfully requests entry of amended independent Claims 17-19 and 21. Claims 17-19 and 21 have been amended to further describe Applicant's invention. Support for such amendments may be found throughout the specification,at,e.g.paragraphs[[0001],[0023],[0025],[0026], [0031],[0032],[0035],[0038][0039],[0073],[0075],[0077],**Figs.**4,5,7,8,9,11A,11B,12A,12B, 13, 14, 15,16,17,18 and 19. Without acquiescing to any of the contentions in the Outstanding Office Action, it is respectfully asserted that according to amended claim 17 and other claims, present invention *as a whole* is constructed *structurally different* from device of Vicenzi and device of Walker and is used in an entirely *different manner*, thereby overcoming drawbacks in the apparatus of Vicenzi and apparatus and method of Walker individually or combined, as well as many similar devices known in the prior art of record. For example "Vicenzi" does not teach or suggest Intramedullary Pin 1 of *universal length* structure as elastic stems 8 are attached with one rigid stub 2 at one end. With this structure one cannot use same length nail in all the patients with different length of bone in different age group , so according to teachings of Vicenzi one who wants to use Intramedullary pin 1 requires to have all different length size inventory ready all the time for proper operation of Intramedullary pin in different age group and size of patients which is contrarily to disclosure by Applicant . If one imagine to modify Intramedullary pin1 of "Vicenzi.", to make its structure of universal length as claimed in instant claim of application and if one intends to use such modified Vicenzi nail ,one has to cut distal

free ends 9 of stems 8 exactly according to size of patient preoperatively before insertion of intramedullary pin1 in medullary canal of a bone as proximal ends are held rigidly with rigid stub 2 , it will be very difficult to glide leading cut ends (not having gliding tips) in medullary canal which does not serve the purpose as disclosed by Applicant. Modification of Vicenzi nail to make it of universal length structure is not workable and teachings of Vicenzi or Walker individually or combined do not teach or suggest or give any motivation to modify individual flexible nail element of instant claim to have universal length structure to have advantage to surgeon to select nail of any fraction of centimeter to match the length of bone to be fixed without an error. "Vicenzi" teaches Intramedullary pin 1 having elastic stems **8** where each stem 8 is *rigidly attached* with rigid metal stub 2 at one end and each stem 8 having other free end 9 which is *round* (Col.2 ,lines 41-42) in shape at tip having substantially same diameter as shaft part (Fig. 4 and Fig 5).Applicant discloses in amended Claim 17-19 implant assembly with elements of plurality of Intramedullary flexible Nail 19 having *structurally* a shaft 31 , proximal end 32 and distal end 23 where *both* ends are *identical* and *free without any attachment* and both end are having *conical* pathfinder tip 20 which has *cross section diameter less than shaft* part for easy gliding in medullary canal of a bone during insertion . Applicant also points out that Intramedullary Pin 1 disclosed by Vicenzi is having stems 8 *bundled* before insertion into medullary canal of a bone with the help of means 10 comprising metallic wire 11, a manual grip ring 12 rigidly associated with wire 11 at one end and a bent portion 13 engaged on wire 11 defining loop 14 rigidly associated with wire 11 at other end , proximate to the ends stems 8 have respective grooves 15 in which loop 14 can be accommodated while wire 11 runs between stems 8 (Fig 4 and Fig 5) , it becomes very difficult to pass *bundled* nail across the fracture zone without broaching the canal and may require opening the fracture site by putting the cut in skin and structures up to bone at fracture zone leading to *invasion to patient* and have difficulty to unbundle the bundled inramedullary pin by pulling the wire 11 or there may be breakage of wire 11 or there may be breakage of stem 8 at groove 15 which is stress riser point in stem giving the notch effect while unbundling the intramedullary pin 1. Applicant further points out that as taught by Vicenzi proximal ends of stem 8 are rigidly associated with rigid stub there is *no possibility* to *align individual stem* 8 in relation with each other to reposition and align bone fragments of a fractured bone to prevent malrelation of fragments and individual stem end cannot have different curvature at different planes to have multiple

contact points of fixation as they are bundled at end . Applicant further points out that intramedullary pin 1 as disclosed by Vicenzi is having rigid stub 2 rigidly associated elastic stems 8 having stress riser at junction (transitional zone of weakness) of rigid stub 2 and elastic stems 8 leading to breakage at junction while insertion of bundled intramedullary pin 1 or particularly while extracting unbundled intramedullary pin 1. Applicant further points out that Vicenzi teaches Intramedullary Pin 1 having rigid stub 2 and elastic stems 8 rigidly attached with stub 2 are made from 316 L Stainless Steel material but Vicenzi has not disclosed elastic stems 8 or rigid stub 2 having ductility of 15% elongation on tensile stress showing *structural property* of *final finished end product* of Intramedullary Pin 1. Examiner has taken the position (Office Action Page 15) that as Vicenzi 's Intramedullary Pin 1 is made from same material (316L Stainless Steel) as Applicant's Flexible Nail and ductility and ultimate tensile strength are the *material properties* of 316L Stainless Steel-material from nail is made , therefore extrapolated and *speculated* that Vicenzi's Intramedullary Pin is also having ductility of 15% of elongation on tensile stress . Applicant respectfully argues that Flexible Nail disclosed in amended claims 17-20 discloses *structural properties* of Applicant's Nail as final finished end product having *structural property* of at least 15% elongation of nail on tensile stress irrespective to *material property* of source material(for example, 316 L Stainless Steel) from which nail is made. Vicenzi or Walker any other prior art on record individually or in combination does not teach or disclose or motivate or suggest to have structural element of at least 15% of elongation on tensile stress on flexible nail. Applicant respectfully argues that Examiner has possibly *speculated* possibility of this structural limitation of instant amended claim with hindsight of applicant's disclosure itself. Applicant respectfully further argues that "Walker" teaches to have core 13 is made from either *plastic or ultra high molecular weight polyethylene* (Col. 5 ll 20, Col. 6 ll 11-12) and is *flexible relative to pins* 11 (Col 2. ll 6-7) and it *extends across* the fracture zone and *extends along* essentially whole length of pin (Col. 3 ll 48-51, Fig. 1, 2, and 10.). Applicant discloses a *proximal* fixation device which is made from *Stainless Steel Rod* and is *rigid relative to flexible pins* and *does not extend across* the fracture zone (Fig. 11A, 12A, 17, 18 and 19.) and *does not extend along* essentially whole length of flexible pins to have curvatures at different points and in different planes to get multiple contact point fixation inside the medullary canal without disturbing the fracture zone and to have flexible but stable construct. Plastic core 13 relatively flexible to metal pins and metal pins *both*

extending across fracture zone as taught by " Walker" *structurally or functionally* will not be able to allow to have curvatures at different points and planes to get multiple contact points of fixation inside the medullary canal, which is contrary to Applicant's disclosure. Plastic core and metal pins as having sliding fit taught by "Walker" will lead to plastic debris or wear at fracture zone due to friction between different material having different material properties leading to osteolysis – loss of bone at fracture zone which will delay or abort the healing of bone. 'Walker" teaches *sliding fit* of flexible pins in longitudinal grooves of flexible core (Col.5 ll 15-16) allowing sliding and migration of pins proximally and also teaches to keep pins outside the flexible core at proximal insertion point or entry without *any anchorage* with flexible core for easy gripping for removal later on.(Col.3 ll 53-56) which is contrarily to teachings disclosed by Applicant. As Examiner has suggested to replace Vicenzi's fixation device with Walker's fixation device to arrive at claimed invention by one of the ordinary skill in art (Office Action Page 16), Applicant respectfully argues that such combination or replacement does not give any suggestion or motivation to one of the ordinary skill in art to arrive at amended claims 17-20. If as suggested by Examiner one imagine or intends to use Walker's fixation device in place of Vicenzi's fixation device where core 13 is made from either *plastic or ultra high molecular weight polyethylene* (Walker , Col. 5 ll 20, Col. 6 ll 11-12) and is *flexible relative to pins* 11 (Walker , Col 2. ll 6-7) and it *extends across* the fracture zone and *extends along* essentially whole length of pin (Walker ,Col. 3 ll 48-51, Fig. 1, 2, and 10.) wherein plastic core 13 relatively flexible to metal pins and metal pins *both extending across fracture zone* as taught by " Walker" *structurally or functionally* will not be able to allow to have curvatures at different points and planes to get multiple contact points of fixation inside the medullary canal, which is contrary to Applicant's disclosure. Applicant further points out that even with such combination or replacement of parts of cited prior art will not be able to satisfy structural limitation of element of plurality of flexible nails having at least 15 % elongation on tensile stress. As such teachings of Vicenzi or Walker individually or in combination does not provide suggestion or motivation to one of the ordinary skill in art to arrive at claimed *invention as a whole* and thus do not render it obvious. Applicant respectfully requests entry and allowance of Claims 17-22

Claims 25 and 27 are rejected under **35 U.S.C. 103(a)** as being unpatentable over Walker (**US 4,457,301A)** in view of Haas (5,976,140A) and Grotz (5,968,078A). Examiner on page 18 of Office Action pointed that **" Regarding claim 25, Walker discloses that the rod has a head**

portion adaptable to an end cap and temporarily adaptable to a suitable targeting device (bore 22 could receive an end cap and a targeting device) and that the rod tapers to a blunt……..". Applicant respectfully argues that Walker has disclosed flexible plastic core 13 having longitudinal bore 22 to insert core 13 in medullary canal guided on guide pin (Col 4., Line 20-24, Fig 5), but has not disclosed or suggested or motivated to have structural element securely adaptable (for example threads) to engage temporarily to suitable targeting device for targeting purpose or securely adaptable permanently to end cap . Applicant respectfully points out that Examiner has possibly *speculated* possibility of structural limitation of bore 22 *could receive* an end cap and targeting device and suggested such modification in Walker device to show instant claim 25 obvious , wherein Walker has not disclosed , suggested or motivated to have such structural limitation of instant amended claim , possibly examiner has speculated with hindsight of applicant's disclosure itself. Even if such modification of Walker's fixation device having plastic flexible core 13 adaptable securely to targeting device is done and intended for use with such structural limitation , targeting of possible plural holes in such fixation device by targeting device would not be accurate due to very high flexibility of plastic core relative to pins , angles and adjustment with targeting device will change due deflection of plastic core within medullary canal of a bone (for example femur). As such teachings of Walker does not provide suggestion or motivation to one of the ordinary skill in art to arrive at claimed *invention as a whole* and thus do not render it obvious. Applicant respectfully requests entry and allowance of Claim 25.

Conclusion

Consideration for and allowance of the pending claims in this Application, as provided in the Listing of Claims in this paper are respectfully requested for the reasons set forth herein. In light of amendments, remarks and arguments presented with this paper, Applicant respectfully submit that the pending and amended claims are in condition for allowance. No new matter has been introduced with this Amendment.

This amendment is timely filed with request for extension of time under CFR 1.136 and appropriate fees . No additional fees are believed due with this response. If this is incorrect, the Commissioner is authorized to charge such fees, other than the issue fee, that may be required by this paper to Deposit Account No: 20-0674.

The Office is invited to telephone the undersigned representative at (443) 552-7281 (4AM-Noon, voicemail otherwise) if it is believed that an interview might be useful for any reason.

If the Examiner has any question or comments or if further clarification is required, it is requested that the Examiner contact the undersigned.

Respectfully submitted,
/Narendra Reddy Thappeta/
Signature

Date: November 18, 2009

Printed Name: Narendra Reddy Thappeta
Attorney for Applicant
Registration Number: 41,416

~~Description~~

FLEXIBLE NAIL ASSEMBLY FOR FRACTURES OF LONG BONES

Cross-Reference to Related Applications

[001] The present application is related to and claims priority from PCT application PCT/IN2005/000103 filed on 7 April 2005, which in turn claims priority from India Patent Application 438 /MUM/2004 filed on 12 April, 2004, which are both incorporated in their entirety herewith.

Technical Field

[002] The present invention relates to an orthopedic implant assembly used to repair fractures of the long bones particularly in children and in certain conditions in adults by generally more than one flexible intramedullary nails having very high flexibility with high tensile strength and gliding conical pathfinder tip at both ends with optional fixation device for retention of flexible nails at one end and also having in combination temporarily applied at distal end of nail, a tool like plier-knurler cum cutter to get knurling type effect at cut ends of nails.

Background Art

[003] As shown in Fig.1 and 2, Long bones of children like femur (1) and tibia(2) are having growing ends -epiphysis (3)having growth plate(4) ,a nongrowing shaft –diaphysis (5) and intermediate part-metaphysis (6). Injury or irritation to this epiphysis (3) directly or indirectly hampering its blood supply leads to deformity of bone and limb. Treatment of Fractures of long bones of weight bearing lower limb like femur (1)-thigh bone, tibia (2) and fibula -leg bones and non weight bearing upper limb bones like humerus (54)- arm bone, radius (55) and ulna (56) - forearm bones, particularly fractures of shaft or diaphysis (5) many a times require its fixation with nails. To prevent injury to epiphysis (3), entry of such nails required away from the ends of long bone from sides and angled. For such side angled

entry of nails in long bones require very high flexibility. and strength from material of nail. Flexibility of nail is measured indirectly by its ductility, which in turn measured as percentage of elongation of nail during testing of nail on universal testing machine. Strength of nail is measured as stress applied on nail in units of Mega Pascal (MPa) on universal testing machine. Flexibility of nail helps surgeon to have different curves at desired distance and angle to facilitate its introduction in medullary canal (7) and also gives multiple point contact to maintain fracture fragments in correct relation during knitting. Long bones of children are elastic and are having different curvatures. Long bones of children are growing, so it requires removal of nails earliest after solid union of fracture.

[004] Experiences of surgeons and clinical studies and mechanical studies have shown that treatment of fractures of long bones by flexible nails require implant assembly with proper biomechanical properties, such as:

- It requires high flexibility at the same time high strength to get more curvatures and multiple contact points at medullary canal and due to high flexibility it should not require two opposite entry sites to balance opposing force of curvatures.
- It requires path finder gliding tip to glide in medullary canal, not injuring epiphysis or perforating opposite cortex while making entry in medullary canal.
- It should be of universal length to have latitude to surgeon to select any fraction of length suitable for better fixation and at the same time avoid penetration of proximal epiphysis and avoid irritation of soft tissue at distal end of nail.
- It should have facility for surgeon to choose different cross section diameters in combination to get adapted well in any size of medullary canal.
- It should have a non leading or projecting end such that it does not irritate soft tissues around it at the same time provide means for easy removal after solid union of fracture without much difficulty.
- By having multiple curves and multiple contact interference fit, by rotation of nail it should allow rotational or lateral movement of fracture fragments to improve relation and contact between fragments.
- It should allow limited axial loading of fracture fragments without displacement on weight bearing by patient to stimulate bone healing.

- It should not back out at knee or non leading end or penetrate joint on weight bearing by patient.
- It should be minimally invasive to patient.

[005] Along with these biomechanical properties, the implant unit should be easy to fix and should provide maximum accuracy of fixation. So that it is adoptable to average surgeon giving reproducible results. It should be cost effective too.

[006] Nails and like devices for emplacement in the medullary canal of fractured long bones, for maintaining the parts in correct relation during knitting, are known since long.

[007] Rush, U.S. Pat. No. 2,579,968, Dec. 25, 1951, as shown in Fig 3A, 3B, discloses a pin (8) of flexible, resilient material like stainless steel and which is originally straight except for a slight curve or bend at its forward sharpened end (9). The particular feature taught by the patent resides in the shape of the sharpened distal end, by which that end, in penetrating the medullary canal, is cammed free of the cortex during movement there along. Here, flexibility is less and sharp end does not glide easily in medullary canal and penetration of opposite cortex of bone is known to occur. Length of pin (8) is not universal. Hooked end (10) can cause irritation.

[008] Herzog U.S. Pat. No. 2,998,007 Aug. 29, 1961, teaches a stiff rigid steel tube open at both ends and pre-shaped if required by the contour of the particular bone to be repaired. The tube is longitudinally slotted at spaced locations along its length. Once emplaced, through an incision at the proximal end of the bone, spring wires are pushed into and through the tube and manipulated so that their ends project from appropriate ones of the slots to become anchored in the cancellous. Thus the patented device is relatively complicated, difficult to install and properly manipulate. Apparently it immobilizes the patient's joint at the proximal end of the bone.

[009] Another prior art device is shown by Fischer et al., U.S. Pat. No. 3,779,239, Dec. 18, 1973, showing a complicated structure including a rigid tube or sleeve pre-shaped to conform to the normal shape of that particular bone. At its distal end the tube carries an expansible section. When the tube and its expansion section are driven into the bone canal through an incision at the proximal end thereof, a rod in inserted into and along the tube, then threadedly attached to the terminal expansion section. Turning of the rod further then causes the expansion of the section to anchor the device within the bone. The device thus shown is complicated and expensive. During emplacement lateral thrust engendered by turning of the flexed rod, tends to cause undesirable transverse movement of the fractured parts due to tendency of the tube to shift or turn in and with respect to the medullary canal. The expense and difficulty in storage of the large number of such devices necessary to service any fractured bone of the body, are clear.

[0010] Ender et al., U.S.Pat. No. 4,169,470, Oct. 02, 1979, as shown in Fig 3C, 3D, discloses thin, flexible, elastic, resilient Ender nails (11) pre-shaped for an adult femur curvatures, fixed length from 32 to 49 cm, preferably of diameter of 4.5 mm, having pointed proximal end (12) and flat eye shape (13) at distal end .It is made of metal having elasticity between about 125 Kp/mm.sup.2 to 145 Kp/mm.sup.2 (claim no. 21).

[0011] After fixation it gives three point fixations due to its curvatures (14). After final fixation with multiple Ender nails (11) at the distal end being flat to permit a fish-scale type mating overlying with the distal ends of a plurality of other similarly shaped nails when protruding in situ through the incision in the bone .One of the disadvantage is the flattening at the distal end which are oriented transversely to the axis of curvature and which are in addition provided with an aperture for the purpose of obtaining an effective engagement of a drive-in tool, may be effective in the manner of a chisel if they do not come to lie completely flat against the bone and in parallel therewith, respectively. The relatively sharp edges formed in this manner may have an irritating effect on the adjacent tissue. As the flattening is normally formed in an upsetting process, additional processing is required so as to remove any burrs or sharp edges formed in said upsetting step. Through the

flattening of a round nail cross sectional area, in addition, a critical zone of transition (15) will form having a relatively high notch effect, so that with a considerable amount of torque applied at the distal end (13) a plastic deformation or even a shearing off may be the result in this zone. Upon rotation of the distal ends (13) against each other, several flattened distal ends require a relatively great amount of space, whereby the well being of the patient may be affected. Problems with this nails are it is stiffer for use in pediatric long bones, not having enough flexibility leading to straightening of curvatures of bones, pointed end (12) many a times penetrates super-adjacent fracture fragment and penetrate in hip joint (21), which is considered to be a serious complication of the method of treatment rendering it ineffective. On axial loading by weight bearing on limb, due to insufficient ductility or flexibility, it backs out at distal end thereby increases tissue irritation already present at protruding distal end. Other disadvantages are its pre-shaped curvatures not suitable for long bones of children and lesser diameter than 3 mm is routinely required for narrow medullary canals of long bones of children and in certain occasions in adults having poliomyelitis or narrow medullary canal due to other reasons.

[0012] Kalmert. U.S.Pat. No. 4,473,069, Sep. 25, 1984, showing similar nails as Ender's nail (11), but it is having a means for prevention of back out of nail, having a separate element, a coupling piece with a plate portion which can be mounted to the outside of the bone by means of one or more cross screws. A coupling hook projects from the plate portion, which forms a cross head and can be brought to engage lockingly the elastic nail by the cross head being passed through a slot in one end of the nail and being rotated. Other disadvantages are same as Ender's patent.

[0013] Harder et al. (U.S.Pat. No. 4,712,541, Dec. 15, 187) showing improvisation of Ender's nail (11) by providing a distal end without eye and a proximal end or tip of nail as a rounded-off thickened portion in place of a sharp slanted tip. Other disadvantages are same as Ender's patent.

[0014] Walker, U.S.Pat. No. 4,457,301, Jul. 03, 1987 , shows an intramedullary bone fracture fixation device comprising a plurality of thin resilient pins substantially longer than the fracture zone to be fixed and a flexible core element holding the pins apart from one another in a desired special arrangement over substantially the full length of the pins, with said pins being held in sliding fit in longitudinal grooves in the periphery of said flexible core, wherein the pins are made of titanium alloy Ti-6Al-4V, and the core is made of ultra-high molecular weight polyethylene. Wear of plastic will cause osteolysis. It does not provide any firm anchorage to proximal ends of pins. Due to titanium alloy and ultrahigh molecular weight polyethylene cost of device becomes very high, not affordable to all patients.

[0015] Hinze PCT/EP98/01018, Publication No. WO 98/36699, Aug. 27, 1998 shows a fracture nail made of a nickel-titanium alloy which is plastically deformable at a temperature lower than the human body temperature and which returns to its original shape at the body temperature. At the body temperature, the fracture nail has at least one deviation from its straight central axis and at a lower temperature it can be brought to a substantially straight shape. The fracture nail can thus be firmly braced within the medullary cavity and fully stabilizes the bone. Disadvantages with this nail are it has thermal mechanical-shape memory at particular temperature only which is difficult to maintain many times during surgery, it has no latitude to surgeon to give desired curvature according to site of fracture. Practically to use this nail is very difficult and due to use of shape memory alloy cost is also high. The ends of nail are sharp pointed. Other examples of use of shape memory alloy are Levy, U.S.Pat. No. 6,783,530, Aug. 31, 2004 and Cheung et al., U.S.Pat. No. 20040230193, Nov. 18, 2004.

[0016] Burkinshaw et al., U.S.Pat. No. 6,551,321, Apr. 22, 2003 shows an orthopedic implant including a pair of spaced apart end caps, which are interconnected by a plurality of elongated flexible members. Each end cap includes an aperture formed there through for the use of a trochanteric guide wire for piloting the implant during trial insertion and final insertion into an intramedullary canal. At least one of the end caps includes a rounded end to

enhance insertion. Preferably, the flexible members are bowed outwardly to provide a "birdcage" configuration. Disadvantage of this nail is, it is having rigid part at both end secured with flexible part, having flexibility in particular part only ,thus not allowing entry point of nail at side and angled to side of long bones of children to prevent injury to epiphysis. It is not having universal length, so requires large inventory of different length and different diameter combination.

[0017] Presently used Titanium Elastic Nails (TENs) (16) marketed by Synthes (Paoli, P.A., U.S.A.) are elastic nails made of titanium alloy and recommended for use in fractures of long bones of children. These nails are available in different diameter from 2.5 mm to 4.5 mm, having universal length of 45 cm. As shown in Fig 3E, it is having a leading or proximal end (17) made flat and bent like hockey stick for entry into medullary canal (7). Distal end (18) is rounded. Through the flattening of a round nail cross sectional area, in addition, a critical zone of transition (15) will form having a relatively high notch effect, so that with a considerable amount of torque applied at the distal end (18) a plastic deformation or even a shearing off may be the result in this zone. Other disadvantages are it is made of soft material of titanium alloy having been reported breakage of nail on repeated bending and straightening while insertion or removal. It is reported in study (J.M. Flynn et al.,Journal of Pediatric Orthopedics, Vol.21,No.1 ,2001 Page, 4-8) that TEN(16) technique requires balancing the forces of the two opposing flexible nails. For the same it requires contour of the nails with an identical gentle curvature, and have to use two different, medial and lateral starting or entry points that are at the same level in the metaphysis (6). It is further reported that to balance it requires same diameter opposing flexible nails to prevent mal-relation of fracture fragments like varus and valgus. It is also reported that for easy removal of nails when required, it is recommended to bend a little distal end to facilitate the application of removal device later on. This bent extra_osseous part causes local tissue irritation and pain. Proximal end having flat hockey stick shape (17) bend can cause difficulty in smooth gliding of nail in medullary canal (7) and surgeon has no intraoperative latitude to change the angle of bend according to angle of entry point. Tested on universal testing machine, 3 mm Titanium Elastic Nail (16)

shows percentage of elongation only 8% on tensile stress applied, which is the indirect evidence of ductility or elasticity. Test also shows Ultimate Tensile Strength of 1211.14 MPa. Problem of requirement of balancing force of two opposing nails of same diameter having identical curvature with same level two different entry points to prevent mal-relation of fracture fragments is probably due to low flexibility of nails. This nail is made of titanium alloy, which makes its cost high.

[0018] Mechanical and clinical studies undertaken by inventor have revealed technical problems and disadvantages with prior art.

Disclosure of Invention

Technical- Problems

[0019] 1. As mentioned in background of art, a flexible nail to be used for long bones of children requiring side angled entry requires utmost flexibility or elasticity. Prior art nails or pins does not provide required ductility (percentage of elongation on mechanical testing) leading to either difficult entry as in Rush pin (8), straightening of curvatures of bone as in Ender's nail (11), requirement of opposing balancing nails of identical curvature of almost same cross section diameter having two different entry points at same level or otherwise possible mal-relation of fracture fragments as in - TENs (16)

[0020] 2. Prior art flexible nails are having design of tip of leading end either sharp (9) or slanted sharp (12) or pre-bent flat hockey stick shape (17) which many a times makes gliding of nail in medullary canal (7) difficult and may cause perforation of super adjacent bone fragment or epiphysis or cause perforation in joint (21) making purpose of surgery ineffective. Sharp (9,12) or flat tip (17) gets lodged at concomitant small undisplaced fracture line in fracture fragment and broaden fracture line, thus causing further malrelation of fracture fragments.

[0021] 3. Distal ends of prior art nails are having means for removal like hook end (10) as in Rush pin (8) or flattened eye (13) as in Ender's nail (11) or little bend given to extra osseous part or kept 2cm more out in Titanium Elastic Nail (16), all

cause irritation of soft tissue at distal end. There is no means provided for removal of nails which make removal of nails technically easy at the same time does not irritate soft tissue.

[0022] 4.Flexible nails taught in prior art gives stability in medullary canal of long bones at generally three points by its contact with inner surface of medullary canal (7) which is not adequate in unstable fractures where either there are multiple pieces of bone or supporting soft tissues are also disrupted.

[0023] 5.Flexible nails taught in prior art like Ender's nail (11) is having distal end (13) made flat from round cross section rod and proximal end (17) or leading end of Titanium Elastic Nail (16) is made flat hockey stick shape from round cross section rod. Through the flattening of a round nail cross sectional area, a critical zone of transition (15) will form having a relatively high notch effect, so that with a considerable amount of torque applied at the distal end a plastic deformation or even a shearing off may be the result in this zone.

[0024] 6.Flexible nails taught in prior art like Ender's nail (11) and Rush pin (8) are made from stainless steel material are stiffer but having low cost, while Titanium Elastic Nails (16) are made from softer titanium alloys with little more flexibility with possibility of breakage and also having high cost. Flexible nails made from titanium- ~~nickle~~ nickel alloys with thermal mechanical memory are costlier than above all.

[0025] 7.Flexible nails taught in prior art fail in situation where fracture pattern is unstable due to multiple pieces of bone or supporting soft tissues are also disrupted as it does not provide any means for additional rotation stability which is required in such situation.

Technical - Solutions

[0026] 1. Invention provides straight flexible intramedullary nail (19) of universal length of 50 cm having 15 to 25 % of elongation on testing on universal testing machine and ultimate tensile strength of about 600 to 800 MPa (Mega Pascal). So it provides more ductility, flexibility with adequate strength.

[0027] 2.Invention provides flexible intramedullary nail (19) with blunt conical pathfinder tip (20) at both ends which glides smoothly in medullary canal (7) of

long bones and does not perforate cortex of fracture fragments or will not penetrate epiphysis (3) or joint (21) and does not widen undisplaced fracture line.

[0028] 3.Invention provides a tool plier-knurler cum cutter (22) for distal end of flexible intramedullary nail (19) where surgeon can cut the nail at a distance of about 1cm from external surface of bone of entry point when nose (34) of plier - knurler cum cutter (22) is touching the external surface of bone without bending the nail and at the same time it makes small superficial cuts-knurling type effect (25) on 1cm of nail protruding from the entry point (24) in bone. On this straight 1cm part of distal end of nail, which is knurled where, suitable tool for removal at the time of removal, will not slip.

[0029] 4. Invention provides flexible nails (19) with high flexibility where curvatures (26) in nail can be made at more than one place on nail and also in more than one planes, so it gives stability by multiple contact points in medullary canal (7) like loaded spring.

[0030] 5. Invention provides flexible nails (19) with uniform round cross section diameter in whole length without any transitional zone of weakness (15) or flattening at either end.

[0031] 6. Invention provides flexible nails (19) made from material like 316 L or 316 LVM stainless steel and cold worked to get more ductility and strength.

[0032] 7.Invention provides flexible nails (19) with additional adaptable proximal fixation device (27) with or without interlocking screws (28), where adaptable device (27) adapts at proximal end of flexible nails (19), which gives additional rotational stability to proximal fracture fragment at the same time allows minimal axial micro motion at fracture site due to its low axial stiffness.

Advantageous Effects

[0033] 1. Due to high flexibility, entry of flexible nail (19) in medullary canal (7) becomes easy and it preserves normal anatomic curvatures of long bones. It does not require opposing balancing identical curvatures and same level two different side entries with use of almost equal cross section diameter of flexible nails. It is introduced with single entry point (24) with lazy "s" shape (29) curvature and "c" shape curvature (30) of any appropriate diameter according to diameter of

medullary canal with good elastic stability and without any malrelation of fracture fragments.

[0034] 2. Prevents injury to super adjacent fracture fragment or epiphysis (3) or joint (21) or concomitant undisplaced fractures. Surgeon can use it from either end and in less height child surgeon can make two nails out of one.

[0035] 3. Provides means for easy removal of flexible nails (19) at the same time does not irritate soft tissue till removal of nail.

[0036] 4. Provides more stability in unstable fracture pattern and prevents malrelation of fracture fragments.

[0037] 5. Provides uniform stability without any plastic deformation or shearing off at either end with torque applied on distal end.

[0038] 6. Provides high flexibility with strength at the same time with lower cost than nails made from material like titanium alloys or shape memory alloys.

[0039] 7. Provides additional rotational stability in unstable fracture pattern or where supporting soft tissues are disrupted and prevents mal-relation of fracture fragments till union of fractures. It allows early weight bearing by patient and also stimulates callus formation at fracture site by axial micro motion.

Description of Drawings

[0040] Fig. 1 shows front view of normal human child's femur bone showing

[0041] Epiphysis, metaphysis and diaphysis and growth plate.

[0042] Fig. 2 shows front view of normal human child's tibia bone showing

[0043] Epiphysis, metaphysis and diaphysis and growth plate.

[0044] Fig. 3A shows side view of Upper end of Rush Pin showing pin bent like hook.

[0045] Fig. 3B shows side view of Lower end of Rush Pin showing sharp bent tip.

[0046] Fig.3C shows front inside view of Ender's Nail showing lower end having flat with eye and critical zone of transition.

[0047] Fig.3D shows side view of Ender's Nail showing lower end flat with eye and critical zone of transition and upper end with predefined curvatures.

[0048] Fig. 3E shows side view of Titanium Elastic Nail showing upper end bent like hockey stick shape and flat with critical zone of transition.

[0049] Fig. 4A shows elevation of proposed Flexible Nail implant showing it straight before insertion in to medullary canal.

[0050] Fig. 4B, 4C and 4D shows side view of proposed Flexible Nail showing different curvatures like lazy "s" shapes and "c" shape when inserted into medullary canal.

[0051] Fig. 5A and 5B shows enlarged view of conical pathfinder tip and plan of nail respectively.

[0052] Fig. 6A shows Plier-Knurler cum Cutter showing its jaws, nose, knurler part of 1cm length, cutting part and handle part.

[0053] Fig. 6B shows enlarged view of distal end of proposed nail showing superficial small cuts on the surface of distal most 1cm of nail -knurling type effect to have easy grip at the time of removal of nail.

[0054] Fig. 7A and 7B shows schematic of child's femur bone showing proposed flexible nails inserted in medullary canal by single entry point from distal and proximal end of bone respectively having multiple points of contact in medullary canal. .

[0055] Fig. 8A and 8B shows schematic of child's tibia bone showing proposed flexible nails inserted in medullary canal by single entry point from proximal and distal end of bone respectively having multiple points of contact in medullary canal.

[0056] Fig. 9 shows schematic of child's humerus bone showing proposed flexible nails inserted in medullary canal by single entry point from proximal end of bone having multiple points of contact in medullary canal.

[0057] Fig. 10 shows schematic of child's radius and ulna bone showing proposed flexible nails inserted in medullary canal by single entry point from proximal end in ulna and from distal end in radius having multiple points of contact in medullary canal.

[0058] Fig. 11A shows elevation of Proximal Fixation Device without holes for interlocking screws showing upper part or head having internal threads, middle part or shaft having longitudinal grooves on surface and ~~tappered~~ tapered round distal end or tail.

[0059] Fig. 11B shows cut section of Proximal Fixation Device at the line AB showing grooves equally spaced apart at four corners of solid shaft part.

[0060] Fig. 12 A shows elevation of Proximal Fixation Device with holes in shaft part for interlocking screws showing upper internally threaded end, middle part or shaft having longitudinal grooves on surface and ~~tappered~~ tapered round distal end or tail.

[0061] Fig. 12 B shows cut section of Proximal Fixation Device at the line XY passing through holes for interlocking screw showing grooves equally spaced apart at four corners of solid shaft part and cut on non grooved part for interlocking screw.

[0062] Fig. 13 shows elevation of end cap showing threaded part adaptable to threaded part of proximal fixation device and head part with holes for holding flexible nails.

[0063] Fig. 14 shows cross section of femur bone with Proximal fixation device inserted in medullary canal showing medullary canal and cut section of proximal fixation device showing grooves at periphery for flexible nails.

[0064] Fig. 15 shows cross section of femur bone with Proximal fixation device inserted in medullary canal and flexible nails passed in peripheral grooves showing medullary canal and cut section of proximal fixation device showing grooves filled with round flexible nails.

[0065] Fig. 16 shows cross section of femur bone a the level of interlocking screw with Proximal fixation device inserted in medullary canal and flexible nails passed in peripheral grooves showing medullary canal and cut section of proximal fixation device showing grooves filled with round flexible nails and cut in non grooved shaft for interlocking screw.

[0066] Fig. 17 shows schematic of front view of adult human femur bone with fracture in shaft of femur showing Proximal fixation device without holes for interlocking screw and flexible nails passed through grooves in proximal fixation device and flexible nails have crossed fracture zone and end cap holding hooked cut ends of flexible nail.

[0067] Fig. 18 shows schematic of front view of adult human femur bone with fracture in shaft of femur showing Proximal fixation device with holes for interlocking screw, flexible nails passed through grooves in proximal fixation device and flexible nails have crossed fracture zone and interlocking screw are

placed transversely in shaft of femur and end cap holding hooked cut ends of flexible nail.

[0068] Fig 19 shows schematic of front view of adult human femur bone with fracture in shaft of femur showing Proximal fixation device with holes for interlocking screw and end cap holding flexible nails passed through grooves in proximal fixation device and flexible nails have crossed fracture zone and interlocking screw are placed obliquely in head and neck of femur bone.

Mode for Invention

[0069] As shown in Fig.4A Flexible Intramedullary Nail is straight having universal length preferably of 50 cm, is having identical proximal end (32) and distal end (23) and part in between two ends is shaft (31). As shown in Fig. 5A and 5B, proximal end (32) and Distal end (23) is having tip (20), which is round in cross section and conical round at end. Conical part is having less cross section diameter than shaft part (31). Purpose of having universal length is to give surgeon intraoperative latitude to have exact length even in fractions of centimeter, so that upper end do not do injury to epiphysis , at the same time lower end does not irritate soft tissue. Purpose of conical round path finder tip (20) is to have very easy gliding of flexible nail (19) in medullary canal (7) and will not penetrate super adjacent fracture fragment or joint (21). Conical pathfinder tip (20) does not get stuck in concomitant undisplaced fractures. Flexible nail (19) can be made from material like 316 L or 316 LVM stainless steel to get strength at the same time to reduce cost. It is processed by cold method to get higher ductility than titanium and also high ultimate tensile strength. It is made by drawing from ingot. Fig 4B, 4C 4D, 7A, 7B, 8A, 8B, 9, 10 shows its flexibility when inserted in medullary canal (7). Final product Flexible Nail (19) should have 15-25% of elongation and about 600 to 800 MPa (Mega Pascal) ultimate strength on testing done by universal testing machine. The nails are the chief stress bearing members of fixation and they must be stiff without being rigid. They must be resilient or flexible to return to their original position when off-loaded axially. In medullary canal (7) when Flexible nails (19) of sufficient in number and diameter are introduced from single distal or proximal entry point (24) generally taking lazy "S" shape (29) or "C" shape (30) in

medullary canal (7) having multiple contact points of fixation. On weight bearing by patient on walking these curves (26) of flexible nails (19) changes, but returns to original shape curves on offloading. Shaft (31) part of flexible nail is round in cross section ranging from 2 mm to 4 mm diameter. Since as previously explained, a plurality of nails may be employed in one operation; the actual effective diameter is to be calculated and may, in fact, vary in accordance with the preference of the surgeon. One surgeon might prefer to use a single nail of greater diameter while another might choose to use two or more of lesser diameter or combinations of different diameter. Due to its flexibility it gives total freedom to surgeon to choose single entry point (24) and to have different combinations of diameter or curvatures (26).

[0070] A plier-knurler cum cutter (22) as shown in Fig.6A comprises jaws (33) having nose (34), knurler surface (35) of 1cm length, a cutting part (36) and handle part (37). After final insertion of flexible nail (19), knurler part (35) holds the 1cm of nail while nose (34) touching the external surface of bone of entry point (24), on pressing by handle (37) knurler part (35) makes small superficial cuts on the surface of ~~holded~~ held 1cm of flexible nail, at the same time cutting part (36) cuts the nail (19) leaving only 1cm protruding from entry point. Finally, as shown in Fig 6B it gives knurling type superficial cuts (25) on nail (19) making it technically easy to remove at the time of removal at the same time as only 1cm of nail (19) is protruding outside the entry point, it will not irritate soft tissue and will not cause pain to patient.

[0071] Optional Proximal Fixation Device (27) with or without interlocking screws (28) and End cap (38) are be used with plurality of above described flexible nails (19). As shown in Fig. 11A, 12A, preferred proximal fixation device (27) comprises of Proximal or Head part (40), Intermediate or shaft part (41) and distal or tail part (42). Proximal fixation device is solid intramedullary rod (39) made from suitable stainless steel or other compatible material to be passed in medullary canal (7) of suitable diameter where cross section diameter is different at head part (40) and tail (42) part. Head part (40) is having internal threads (43) for temporary adaptation of suitable targeting device for interlocking option and for permanent adaptation of externally threaded part (44) of end cap (38). As shown in Fig. 11A,

11B, 12A, 12B, Head (40) and Shaft (41) is having 2 - 4 grooves (45) extending whole length equally spaced from each other around periphery. These grooves (45) serve to guide the flexible nails (19) into place on insertion and to hold them in an approximately parallel position to support the fracture during healing. The longitudinal grooves (45) can have various cross-section forms, but must give lateral support to the pins and have a depth of less than one nail diameter. This shallow depth ensures that the sides of the nails will project radialy out from the surface of proximal fixation device (27) as longitudinal ridges. To have easy insertion of the proximal fixation device (27) into the medullary canal (7) of a bone, the distal end or tail (42) of the device is tapered to a blunt rounded point. Proximal fixation device (27) is 9-13mm. in diameter with two to four longitudinal grooves (45) each about 3 mm. wide and about 1.2 mm. deep. As shown in Fig. 12 A, when proximal fixation device (27) with holes (46) for interlocking screws (28) is preferred, number of grooves (45) will be at least two. However, proximal fixation devices will range from about 9-13 mm. Diameter and about 65 - 220 mm. in length with different number of grooves (45) in different combinations according to requirement and choice of surgeon. As shown in Fig 14,15 and 16 cross section of proximal fixation device (27) as if it assembled in medullary canal (7) of femur (1) bone without flexible nails (19), with four flexible nails (19) and with flexible pins (19) and hole (46) for interlocking screw (28) successively. Optionally as shown in Fig 12A and 12 B, Proximal fixation device (27) may have plurality of through hole transversely or obliquely placed in shaft (41) part for interlocking screw (28). Proximal fixation device (27) in use with combination with plurality of flexible nails (19) gives increased stability of the fracture during healing. The stress bearing nails are held at the periphery of the medullary canal (7), where they can best resist torsional (twisting) and flexural loads with optional interlocking screw (28). It increases stability at the same time preserves springiness of flexible nails (19) without hampering endosteal vascularity of fracture fragment, as insertion of flexible nails does not require broaching of canal. It gives sufficient control of transverse, torsion and flexural stress to prevent displacement of fracture ends, but not such complete control as to eliminate those stresses below a level beneficial to healing. The proximal fixation device (27) with multiple flexible nails

(19) of this invention has relatively low resistance to axial movement in the bone. Therefore, it allows some axial impaction of the fracture, which also aids the healing process.

[0072] As shown in Fig. 13 End cap (38) comprises of Head part (47) and Shaft or threaded part (44). Head part (47) is having generally round cross sectional diameter larger than shaft part (44) and is having plurality of holes (48) for adaptation of ends of flexible nails (19) to be hooked (53) with it. Shaft part (44) is having small diameter externally threaded portion to be have final attachment with internally threaded part (43) of proximal fixation device (27). Purpose of end cap is to give proximal anchor and to retain hooked ends (53) of multiple flexible nails (19) to add stability.

Best Mode of Invention

[0073] In case of fracture of shaft femur in child the proposed implant is implemented in the manner given below:

[0074] First of all patient is positioned on fracture table and anatomical reduction of shaft femur fracture is done and confirmed with imaging device in both planes known to those ordinarily skilled in art. Local parts are prepared and draped to get sterile field as per usual manner known to person skilled in art. Short length incision is made on lateral aspect of lower thigh. An angled appropriate hole is made in lateral cortex of femur 2 cm above the epiphysis (3) as known to person skilled in art. Flexible nail (19) of appropriate diameter is mounted on suitable T-handle tool known to those skilled in art. A slight bend is given at the end of flexible nail (19) to facilitate entry in the medullary canal (7) and desired curvatures (26) are given gently .Now the nail (19) is inserted in medullary canal (7) under observation with imaging device by gentle rotatary and push movement .It glides very smoothly in medullary canal. Now it is passed to opposite fragment over fracture zone (52) .On gradual passing to super adjacent fragment it automatically

improves relation of fracture fragments. Now it is hammered to final position to dense metaphyseal (6) bone. After final fixation 1 cm of nail is kept out with knurling effect (25) with the help of plier-knurler cum cutter (22) to have a grip of nail at the time of removal at the same time not irritating soft tissues at lower end of thigh. Successive flexible nails (19) with different curvature (26) are inserted in medullary canal (7) from same lateral entry hole at lower thigh till adequate stability is achieved as shown in Fig. 7A.

[0075] As shown in Fig. 7B, entry site may be chosen by surgeon at upper end of thigh for fracture of femur (1) bone. As shown in Fig.8A and Fig. 8B fractures of Tibia (2) bone can be treated in same manner taking either proximal or ~~and~~ distal entry point respectively. As shown in Fig. 9 fractures of Humerus (54) bone can be treated in same manner with flexible nails. As shown in Fig .10 fractures of Forearm bones radius (55) and ulna (56) can be treated in same manner with flexible nails (19).

[0076] In case of fracture of shaft femur (1) in adult or adolescent the proposed implant is implemented with proximal fixation device (27) with or without interlocking screws (28) in the manner given below.

[0077] First of all patient is positioned on fracture table and anatomical reduction of shaft femur (1) fracture is done and confirmed with imaging device in both planes known to those ordinarily skilled in art. Local parts are prepared and draped to get sterile field as per usual manner known to person skilled in art. An angled appropriate hole is made at upper end of femur and extended to medullary canal (7) by proper reaming up to 65 to 220 mm as known to person skilled in art. Now a proximal fixation device (27) is mounted on targeting device. Keeping tail (42) end as leading end proximal fixation device (27) is inserted in to medullary canal (7) by gentle push and rotatary movement. Now flexible nail (19) is inserted through one of the longitudinal grooves (45) around periphery of proximal fixation device (27) and pushed down and rotated to desired position in lower metaphysis (6) of femur (1). Same procedure is repeated by introducing another flexible nail (19) having different direction of rotation passing through another groove (45). Now after final insertion flexible nails (19), protruding out nails are cut .Now through the holes (48)

in end cap (38) cut ends of flexible nails (19) are passed and threaded part (44) of end cap is adapted well with internally threaded part (43) of head (40) of proximal fixation device(27). Cut ends of Nails (19) are bent like hook (53) and finally hammered to rest upon and hooked to the periphery of head part (47) of end cap (38) as shown in Fig. 17. In cases where additional rotational stability is required, fixation device with holes (46) in shaft part (41) is selected and interlocking screws (28) are passed transversely as shown in Fig 18 or obliquely in to head (51) and neck (50) of femur (1) as shown in Fig. 19.

[0078] Postoperatively patients are allowed to have pain oriented weight bearing. Initially implant takes full load of different forces acting on femur and it reacts effectively by allowing limited axial collapse of fracture gap leading to early bone to bone contact and healing. In this way, gradually the implant diverts the above said load to fractured femur bone stimulating healing of femur bone without any postoperative setbacks.

[0079] Those of ordinary skill in the art will further understand and appreciate from the totality of the foregoing disclosure, that the various alternative features and components shown and discussed in conjunction with Fig. 1 through 19, may be practiced in accordance with various installation and withdrawal methodologies, all of which combinations are intended to come within the spirit and the scope of the present invention, without rediscussion thereof. Such alternative methodologies are intended to include the use of different flexible nail and proximal fixation device embodiments practiced in accordance with the invention. It should be further understood by those of ordinary skill in the art that the foregoing presently preferred embodiments are exemplary only, and that the attendant description thereof is likewise by way of words of example rather than words of limitation, and their use does not preclude inclusion of such modifications, variations, and/or additions to the present invention (either apparatus or methodology) as would be readily apparent to one of ordinary skill in the art, the scope of the present invention being set forth in the appended claims.

Industrial Applicability

[0080] An orthopedic implant of Flexible Nail alone or in combination with Proximal Fixation Device with or without interlocking screws of the present invention is biomechanically a superior method of treating a wide range of fractures of shaft of long bones in children or adults. It can be used for reconstruction of the shaft of long bones, allograft reconstruction of the shaft of long bones after tumor resection, and leg lengthening. Other uses will be recognized by those skilled in the art.

Claims

[1] An orthopedic implant assembly comprising:

A straight flexible nail of universal length being adapted in use for insertion into intramedullary canal of long bones for repositioning and fixing fragments of bones having ductility of 15-25% of elongation of nail on tensile stress and about 600 to 800 MPa ultimate tensile strength and made of stainless steel material having identical two ends and shaft where said ends are having blunt conical pathfinder tip and said shaft and said ends are having flexibility such that it can be bowed to any angle or curvature to adapt medullary canal and maintain relation of fragments of long bones having multiple contact points of fixation;

an optional proximal fixation device being adapted in use for insertion into medullary canal of long bones in combination with plurality of said flexible nails where said proximal fixation device is comprising solid intramedullary rod having the plurality of longitudinal grooves being deep less than one said flexible nail diameter and equally spaced around the periphery of the said rod, the said rod having head portion with internal threads adaptable to said end cap and said rod is tapering to a blunt point at the distal end and said shaft of said proximal fixation device is having optional plurality of holes in non grooved part for interlocking screws ;

an optional end cap being adapted in use with said proximal fixation device in combination with multiple said flexible nails where said end cap is comprising head part with plurality of holes for hooking the cut ends of said flexible nail and externally threaded part to be adapted to said internally threaded part of head of said proximal fixation device at final fixation;

and a plier-knurler cum cutter in temporary use when said flexible nails alone are in use comprising jaws with nose ,knurling surface , cutting part and handle part .

[2] An orthopedic implant assembly of claim 1 wherein said flexible nail characterized having mechanical property of ductility as percentage of

elongation in range of 15-25% on tensile stress and at the same time having ultimate tensile strength of about 600 to 800 MPa.

[3] An orthopedic implant assembly of claim 1 wherein said flexible nail characterized having made from material like 316 L or 316 LVM stainless steel or other biocompatible material.

[4] An orthopedic implant assembly of claim 1 wherein said flexible nail characterized having identical two said ends are having said blunt conical pathfinder tip for better gliding in medullary canal.

[5] An orthopedic implant assembly of claim 1 wherein said proximal fixation device characterised having said solid intramedullary rod having plurality of said longitudinal grooves where said grooves being deep less than one said flexible nail diameter and equally spaced around the periphery of said rod for holding said flexible nails apart from one another.

[6] A proximal fixation device of claim 1 and 5 characterised having said solid intramedullary rod wherein said solid rod is made from material like 316 L or 316 LVM stainless steel or other biocompatible material.

[7] A proximal fixation device of claim 1 and 5 characterized having said solid intramedullary rod wherein said rod is tapering to a round blunt point for easy insertion into medullary canal.

[8] A proximal fixation device of claim 1 and 5 characterised having said solid intramedullary rod wherein said rod is having plurality of said through holes in non grooved part of said shaft part placed in either transverse direction or an oblique direction to long axis of said shaft part of said proximal fixation device to receive said interlocking screws.

[9] An orthopedic implant assembly of claim 1 wherein said plier-knurler cum cutter is characterised having said nose part, said jaw part having said knurler

surface to give said knurling type effect to cut ends of said flexible nail and cutting part to cut the said flexible nail at the distance of 1 cm when said nose part is touching the said entry point on surface of bone where said jaws are holding said flexible nail.

[10] A flexible intramedullary nail comprising:

a proximal fixation device characterised having solid intramedullary rod tapering to round blunt point and having plurality of longitudinal grooves where said grooves being deep less than one said flexible nail diameter and equally spaced around the periphery of said rod in combination with; multiple flexible nails characterised having mechanical property of ductility as percentage of elongation in range of 15-25% on tensile stress and at the same time having ultimate tensile strength of about 600 to 800 MPa and having identical two ends and shaft where said ends are having blunt conical pathfinder tip and said shaft and said ends are having flexibility such that it can be bowed to any angle or curvature to adapt medullary canal and maintain relation of fragments of long bones having multiple contact points of fixation ; a end cap being adapted in use with said proximal fixation device in combination with multiple said flexible nails where said end cap is comprising head part with plurality of holes for hooking the cut ends of said flexible nail and externally threaded part to be adapted to said internally threaded part of head of said proximal fixation device at final fixation.

[11] The flexible intramedullary nail as defined in claim 10 wherein said proximal fixation device, said multiple flexible nails and said end cap are made from material like 316 l or 316 LVM stainless steel or other compatible material.

[12] A method of stabilizing a fracture of a long bone of a patient comprising the steps of:

(a) An inserting proximal fixation device without holes for interlocking screws provided with a plurality of longitudinal grooves in the periphery thereof into the medullary canal of the fractured bone ; and

(b) then inserting a flexible nail into each of said longitudinal grooves so that said pins are held apart in compression between the patient's bone structure and said proximal fixation device in a desired special arrangement over short lengths of said flexible nails, with said flexible nails and said proximal fixation device being positioned ,at the completion of said step (b),said flexible nails are extended through the fracture zone and into the medullary canal of sound bone on both sides of the fracture; and

(c) then said end cap having plural holes in head part is attached to said proximal fixation device and said flexible nails are cut and hooked in said holes of said end cap.

[13] A method of claim 12 wherein said proximal device, said flexible nails, said end cap are made of metal, said proximal fixation device has a blunt pointed distal end and said proximal device is having internally threaded part to mate with externally threaded part of said end cap, said flexible nails are of circular cross section with pathfinder blunt conical tips, and said longitudinal grooves are equally spaced around the periphery of said proximal fixation device and are each of a depth less than one diameter of the nail received thereby.

[14] A flexible interlocking intramedullary nail comprising:

a proximal fixation device characterised having solid intramedullary rod tapering to round blunt point and having plurality of longitudinal grooves where said grooves being deep less than one said flexible nail diameter and equally spaced around the periphery of said rod and non grooved part of shaft part is having plural holes for interlocking screws in combination with; multiple flexible nails characterised having mechanical property of ductility as percentage of elongation in range of 15-25% on tensile stress and at the same time having ultimate tensile strength of about 600 to 800 MPa and having identical two ends and shaft where said ends are having blunt conical pathfinder tip and said shaft and said ends are having flexibility such that it can be bowed to any angle or curvature to adapt medullary canal and maintain relation of fragments of long bones having multiple contact points of fixation ;a end cap being adapted

in use with said proximal fixation device in combination with multiple said flexible nails where said end cap is comprising head part with plurality of holes for hooking the cut ends of said flexible nail and externally threaded part to be adapted to said internally threaded part of head of said proximal fixation device at final fixation; and plural interlocking screws .

[15] A method of stabilizing an unstable fracture of a long bone of a patient comprising the steps of:

(a) An inserting proximal fixation device mounted on targeting device provided with a plurality of longitudinal grooves in the periphery and plural holes in non grooved part thereof into the medullary canal of the fractured bone; and

(b) then inserting a flexible nail into each of said longitudinal grooves so that said pins are held apart in compression between the patient's bone structure and said proximal fixation device in a desired special arrangement over short lengths of said flexible nails, with said flexible nails and said proximal fixation device being positioned ,at the completion of said step (b),said flexible nails are extended through the fracture zone and into the medullary canal of sound bone on both sides of the fracture; and

(c) then said end cap having plural holes in head part is attached to said proximal fixation device and said flexible nails are cut and hooked in said holes of said end cap ; and

(d) then said interlocking screws are passed through said holes in said proximal fixation device either in transverse direction or angled direction.

[16] A method of claim 15 wherein said proximal device, said flexible nails, said end cap, said interlocking screws are made of metal, said proximal fixation device has a blunt pointed distal end and said proximal device is having internally threaded part to mate with externally threaded part of said end cap, said flexible nails are of circular cross-section with pathfinder blunt conical tips, and said longitudinal grooves are equally spaced around the periphery of said proximal fixation device and are each of a depth less than one diameter of the nail received thereby and said proximal fixation device is having plural holes.

Abstract

An implant assembly of flexible nails for fractures of long bones comprises of a straight universal length flexible nails having properties of ductility as 15 to 25% of elongation of nail and ultimate tensile strength of 600 to 800 Mega Pascal on testing , wherein each of flexible nail is having an identical pathfinder blunt conical tip at both ends . Aan optional proximal fixation device to be used in combination with flexible nails having peripherally spaced plural grooves and optional plural holes for interlocking screws wherein each groove is deep less than diameter of one of flexible nails. with optional plural holes for interlocking screws to be used in combination with said flexible nails having peripheral equally spaced plural grooves deep less than diameter of one said flexible nail , Ana end cap with plural holes to be used in combination with said proximal fixation device to anchor cut hooked ends of said flexible nails. and a A tool plier – knurler cum cutter temporarily applied when said flexible nails are alone in use.